REMARKS

Restriction /Election

Applicants note that the restriction requirement has been maintained and has been made final. Applicants have maintained the withdrawn claims so that they may be rejoined when allowable subject matter has been identified. The restriction requirement required restriction within a single claim which Applicants maintain is improper.

Claim Rejections -35 USC §112, 2nd paragraph

Claims 8-16

The examiners comments regarding the functional language in claims 8-16 are noted and appreciated. This language further defines the medicaments claimed by reciting a particular use. Applicants submit this additional language does not render the medicaments claimed indefinite. Before canceling these claims Applicants will consider whether this functional language is of any value when allowable subject matter has been identified.

Claims 1-2, 6-16

The term "Chapter" in conjunction with Roman numerals I –IV, identifies the formulas for which they are defined. For example R^1 (Chapter II) is a distinct radical from R^1 (Chapter III). These radicals are defined on pages 11 and 15, respectively. Applicants will consider renaming these radicals once subject matter otherwise allowable is identified.

Claims 1, 6-16 and claims 2-4

Applicants acknowledge that the structures provided do not follow conventional rules but submit that one skilled in the art would recognize the number sign represents a bridge and not a carbon atom (as the Examiner has) when the specification is considered as a whole, such as the structure of formula I in dependent claim 2. Applicants are reluctant to modify the structures in that the application has published and these structures are used in international applications. Applicants would prefer that the structures in these applications remain consistent.

Claim Rejections - 35 USC §102

Claims 1-4, 6-16

Applicants submit these claims are distinguished from the compounds of WO 03095420 by the provisos recited in the claim 1 for Q_1-Q_4 (Chapter I), the definition of R^1 (Chapter II) or the definition of Q_1-Q_3 (Chapter IV), such that there is no anticipation.

For the compounds defined by the first structure for A, the provisos require "when Q_1 and Q_4 (Chapter I) are both methylene and R^3 (Chapter I) is hydroxy, R^2 (Chapter I) is hydroxy, C_{1-6} alkoxy or C_{1-6} alkanoyloxy." In the compounds illustrated on page 5 of the office action, where R^3 is hydroxy, R^2 is hydrogen and **not** "hydroxy, C_{1-6} alkoxy or C_{1-6} alkanoyloxy" such that they do not anticipate compounds where A is the first structure of the claims herein.

For the compounds defined by the second structure for A, R^1 is cycloalkyl or phenyl substituted by heteroaryl or heteroaryloxy or fused by heteroaryl or heterocyclyl. The compounds illustrated on page 5 of the office action do not have such groups for R^1 such that they do not anticipate compounds where A is the second structure of the claims herein.

For the compounds defined by the third structure for A, one of Q_1 -Q_3 is nitrogen. The compounds illustrated on page 5 of the office action do not have nitrogen in the tetrahydronaphthylene structure such that they do not anticipate compounds where A is the third structure of the claims herein.

Claim Rejections - 35 USC §103

Claims 1-2, 6-16

The "tetrahydronaphthylene" compounds of claims 1-2 and 6-16 have substituents or a nitrogen atom which are not shown or suggested by JP04178362 and JP 04178363 and are unobvious in view of these references.

It is alleged that replacing hydrogen of the tetrahydronaphthylene compounds of JP04178362 and JP 04178363 with a methyl group would be obvious. No evidence has been cited which would lead one skilled in the art to make this substitution and expect success. The art the examiner refers to for guidance and/or motivation for this substitution is unrelated to the art of tetrahydronaphthylene compounds. Therefore, substituting hydrogen substituents on the tetrahydronaphthylene compounds of JP04178362 and JP 04178363 would not be

obvious. Changing the mere position of a substituent can render a compound sufficiently distinct to be non-obvious if success would not be expected. See Procter and Gamble v. Teva Pharmaceuticals (Court of Appeals for the Federal Circuit, 08-1404).

In addition, the claimed compounds are distinguished by more than replacing a hydrogen with a methyl group. The substituents R^2 and R^3 (First structure for A Chapter I) on the moiety A (which includes tetrahydronaphthylene derivatives) do not include methyl groups. The substituent R^1 (Second structure for A Chapter II) includes complex cyclic structures and Q_1-Q_3 (Third structure for A Chapter IV) require a nitrogen in the tetrahydronaphthylene ring structure. In that the cited references and evidence relied on do not show all of the claimed features, a showing of prima facie obviousness has not been made and the rejection under 35 USC 103 should be withdrawn.

Claims 1, 6-16

Claims 1 and 6-16 are allegedly obvious in view of the tetrahydronaphthylene compounds of US 6863647 for the same reasons set forth for JP04178362 and JP 04178363. It is alleged that replacing a hydrogen of US 6863647 with a methyl group would be obvious. As with the rejection based on JP04178362 and JP 04178363, the examiner cites no evidence within US 6863647 which would lead one skilled in the art to make this substitution and relies instead on teachings within unrelated arts. There is no evidence one skilled in the art would expect a compound of US 6863647 substituted by methyl to provide useful compounds. Also as discussed above, the compounds of claims 1 and 6-16 vary in structure from those of US 6863647 by more than a methyl group on the "tetrahydronaphthylene compounds." The tetrahydronaphthylene compounds with substitutents defined by R^2 and R^3 (First structure for A Chapter I) are not shown or suggested by US 6,863,647. The tetrahydronaphthylene compounds with substitutents defined by the complex cyclic structures of substituent R^1 (Second structure for A Chapter II) are also not shown or suggested by US 6,863,647 and compounds where one the tetrahydronaphthylene ring atoms Q_1-Q_3 (Third structure for A Chapter IV) is nitrogen are clearly not shown or suggested by US 6,863,647.

In absence of evidence of these features, the rejection of claims herein under 35 USC 103 is unsupported and should be withdrawn.

Claims 1-3, 6-16

Claims 1-3, 6-16 are allegedly obvious in view of WO 9422807, combined with WO 9745111, Patani and WO 99 37607.

WO 9422807 and WO 9745111 each describe tetrahydronaphthylene compounds without any substituents. Patani is alleged to provide motivation to replace a hydrogen atom with a hydroxyl group and WO 9422807 allegedly shows that hydroxylation of the ion channel is known.

As discussed above with regard to the rejection under 35 USC 102 based on WO 03095420, the claimed compounds require more than substitution of the tetrahydronaphthylene compounds by a hydroxyl group. While the second structure for A defines such a group, the moiety R^1 (Chapter II) is not shown.

Claim Rejections -35 USC §112, 1st paragraph

Claims 1-4, 6-16

It is acknowledged in the office action that the specification provides enablement for using compounds of formula I where R^1, R^4 or R is phenyl, benzyl, CH_2-pyridyl, 1,3-benzodioxolyl, tetrahydronaphthalene, isoxazole, dihydroindene, thiadiazole and indole which are substituted with halogen -CF_3, -OCF_3, phenyl, pyridine, pyridyloxy, alkoxy and alkyl.

With such a broad scope of compounds admittedly enabled and no evidence to refute any of the teachings within the specification, applicants submit the specification is objectively enabling for the full scope of compounds of formula I and the rejection should be withdrawn.

No evidence has been presented that the specification fails to provide adequate guidance in the preparation of the full scope of compounds of formula I, or the preparation of pharmaceutical compositions with such compounds, how to administer pharmaceutical compositions with such compounds of formula I or how to test such compounds for physiological activity related to treatment.

Since the structure of the claimed compounds is clearly defined by formula I, applicants maintain one of ordinary skill in art could synthesize these compounds without undue experimentation relying only on conventional methods known in the art. One skilled in the art would recognize the appropriate starting materials necessary to prepare the claimed compounds without undue experimentation and without any guidance from the specification. No evidence has been presented to the contrary.

As to using the claimed compounds, the specification is clearly objectively enabling in disclosing that the compounds have pharmacological activity (see for example the claims 8-16 with functional language).

The distinctions in chemical properties between the compounds exemplified and those that have not bee exemplified do not diminish the enabling teachings within the specification. The examiner provides no basis why one skilled in the art could not make the full scope of compounds of formula I, test the pharmacological activity of these compounds, prepare pharmaceutical compositions with these compounds, and administer these compounds.

The rejection of Claims 1-4, 6-16_is clearly deficient in general under controlling case law. The courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., In re Marzocchi, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971) (holding that how an enablement teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken as in compliance with the enablement requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein. See In re Marzocchi, supra. No such evidence or reason for doubting Applicants' disclosure has been provided. Only general statements and conclusions are made regarding the guidance provided with respect to the treatment of osteoporosis and inflammation.

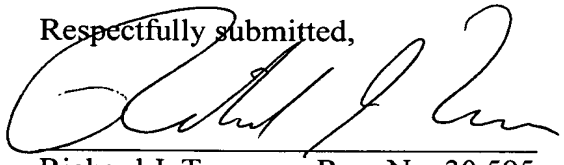
For the reasons stated above, Applicants maintain that they have provided more than adequate guidance to enable the claimed invention and submit all pending claims meet the requirements of 35 U.S.C. §112, first paragraph.

Double patenting

Applicants will address the provisional rejections of Claims 1-4, 6-16 under the doctrine of obviousness type double patenting when allowable subject matter has been identified.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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